DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

Dear Mr. Randolph:

Please refer to your supplemental new drug application dated October 20, 2000, received October 23, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Glucophage® (metformin hydrochloride) Tablets, 500 mg, 850 mg, and 1000 mg.

This "Changes Being Effected" supplemental new drug application provides for a revised patient package insert and package insert necessitated by the approval of Glucophage® XR Tablets, 500 mg (NDA 21-202). Glucophage® and Glucophage XR® share common labeling.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package insert and patient package insert submitted October 20, 2000). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Ms. Jena Weber, Regulatory Project Manager, at (301) 827-6422.

Sincerely,
{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

N2035S22AP